DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION	DOMESTIC ACIDIFIED AND LOW-ACID CANNED FOODS INSPECTION REPORT	CF NO. INSPECTION DATE(S)
LEGAL NAME OF FIRM		FCE NO.
ADDRESS *(Street, City, State, ZIP Code)*		
NAME OF INVESTIGATOR(S)		

SUMMARY OF FINDINGS

SUMMARIZE SIGNIFICANT FINDINGS

HISTORY OF BUSINESS

LEGAL STATUS	IF INCORPORATED (*Give State)*	DATE INCORPORATED
☐ CORPORATION ☐ PARTNERSHIP ☐ OTHER _____		

NAME AND TITLE OF OFFICIALS

RELATED FIRMS

TRADE NAMES/BRANDS

SUMMARY OF PRODUCTS PRODUCED AND USUAL PRODUCTION SEASON(S)

FIRM NAME	CF NO.	INSPECTION DATE(S)

REGISTRATION AND PROCESS FILING

IS THE PLANT REGISTERED PER 21 CFR 108.25(c) OR 108.35(a)? ☐ YES ☐ NO

ARE PROCESSES FILED FOR ALL LACF AND ACIDIFIED PRODUCTS, INCLUDING LOW PRODUCTION ITEMS?
☐ YES ☐ NO IF NO, COMPLETE TABLE FOR PRODUCTS WITH NO PROCESS FILED.

(If additional space is required, use separate sheets)

NOTE: For flexible pouches, report container dimensions as follows: length *(longest dimension)* first, width *(second longest dimension)* second, and thickness *(smallest dimension)* last. Use the same industry convention regarding measurement in inches and sixteenths of an inch as is used for metal containers.

PRODUCT	NET WEIGHT	PACK STYLE	PACKING MEDIUM	CONTAINER DIMENSIONS	DATES PACKED	TYPE OF THERMAL PROCESSING SYSTEM

WERE SCHEDULED PROCESSES ESTABLISHED PER 113.83 OR 114.83? ☐ YES ☐ NO IF NO, EXPLAIN.

IF LACF PROCESSES HAVE BEEN CHANGED, NOTE EXTENT AND BASIS FOR CHANGE AND EFFECTIVE DATE. SEE 108.35 (a)(2)(ii)

HAVE REVISED LACF PROCESSES WHICH REFLECT THE ABOVE CHANGES BEEN FILED WITH FDA? ☐ YES ☐ NO

HAVE THERE BEEN MAJOR EQUIPMENT OR OPERATIONAL CHANGES SINCE THE ORIGINAL PROCESSES WERE ESTABLISHED?
☐ YES ☐ NO IF YES, DESCRIBE BELOW

DESCRIBE PROCEDURES OR WRITTEN PLANS FOR HANDLING PROCESS DEVIATIONS

FIRM NAME	CF NO.	INSPECTION DATE(S)

SCHEDULED PROCESSES AND CRITICAL FACTORS FOR PRODUCTS TO BE COVERED DURING THIS INSPECTION

PRODUCT NAME, STYLE AND PACKING MEDIUM	CAN SIZE	TYPE RETORT	VENT TIME/TEMP.	I.T.	PROCESS TIME/TEMP.	CRITICAL FACTORS AND TARGET VALUES

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

MOST RESPONSIBLE OFFICIAL'S NAME AND TITLE

MAILING ADDRESS *(Street, city, state, ZIP code)*

RESPONSIBILITY	NAME/TITLE
SCHEDULED PROCESS AND MODIFICATIONS	
APPROVAL OF PROCESS RECORDS	
EVALUATION OF PROCESS DEVIATIONS	
RELEASE OF LOTS	
PURCHASE OF EQUIPMENT	
HIRING/FIRING	
QUALITY CONTROL	
FORMULATION AND STANDARDS COMPLIANCE	
OTHER *(Specify)*	

PERSONS INTERVIEWED	NAME/TITLE
SHOWN CREDENTIALS	
RECEIVED FDA FORMS	
ACCOMPANIED INVESTIGATOR	
SUPPLIED INFORMATION	

LIST NAME, TITLE, AGENCY OF ANY OTHER GOVERNMENT INSPECTORS PRESENT DURING THE INSPECTION

FIRM NAME	CF NO.	INSPECTION DATE(S)

FIRM'S TRAINING PROGRAM

FOR LACF, ARE ALL OPERATORS OF THERMAL PROCESSING SYSTEMS AND CONTAINER CLOSURE INSPECTORS UNDER THE OPERATING SUPERVISION OF A PERSON WHO HAS ATTENDED AN APPROVED SCHOOL? *(See 108.35(g) and 113.10)*

☐ YES ☐ NO

FOR ACIDIFIED FOODS, ARE ALL PLANT PERSONNEL INVOLVED IN ACIDIFICATION, pH CONTROL, HEAT TREATMENT OR OTHER CRITICAL FACTORS OF THE OPERATION, UNDER THE OPERATING SUPERVISION OF A PERSON WHO HAS ATTENDED AN APPROVED SCHOOLS *(See 108.25(f) and 114.10 for details)* THE EFFECTIVE DATE OF THIS REQUIREMENT IS SEPTEMBER 16, 1980.

☐ YES ☐ NO

NAME OF OPERATOR	OPERATIONS SUPERVISED OR PERFORMED	SCHOOL ATTENDED	DATE OF CERTIFICATE

RAW MATERIALS

FOR LACF, HOW ARE INCOMING RAW MATERIALS AND INGREDIENTS SUSCEPTIBLE TO MICROBIOLOGICAL CONTAMINATION HANDLED? *(See 113.81(a))*

LIST ALL SOURCES OF EMPTY CANS, JARS AND POUCHES

CONTAINER TYPE SUPPLIER/ADDRESS

DOES THE FIRM PERFORM ANY ACCEPTANCE EXAMINATIONS ON INCOMING CONTAINERS?

☐ YES ☐ NO

LIST SOURCES OF RAW AGRICULTURAL PRODUCTS AND PESTICIDE USAGE DATA

DESCRIBE STORAGE CONDITIONS FOR INCOMING RAW AGRICULTURAL PRODUCTS

GIVE WATER SOURCE(S), DATE AND RESULTS OF MOST RECENT TEST(S) *(Microbiological and chemical contaminants, if performed)*

GIVE IDENTITY AND LEVEL OF FOOD AND COLOR ADDITIVES USED

FIRM NAME	CF NO.	INSPECTION DATE(S)

LIST ANY PRESERVATIVES ADDED TO ACIDIFIED FOODS *(See 114.80(a)(1))*

WASHING AND SORTING

DESCRIBE WASHING AND SORTING OPERATIONS

BLANCHING

(Firm should avoid thermophilic growth temperatures, 122-131 degrees F. (See 113.81(b))

EQUIPMENT/PROCEDURES

HOW CONTROLLED, CHECKED

DESCRIBE WATER SOURCE *(If live steam contacts product, what boiler additives are used and are they on approved list? (See 21 CFR 173.310.)*

TIME/TEMPERATURE OF BLANCHING	INTERNAL TEMPERATURE OF FOOD AFTER BLANCHING

EMPTY CONTAINER HANDLING

(Caution: Any cans removed from the line for examination should not be returned since flanges could be damaged.)

CONDITION OF EQUIPMENT *(Wear, burrs, etc.)*

WHAT TYPE OF CONVEYOR SYSTEM IS USED FOR EMPTY CONTAINERS?

IF CABLE CONVEYOR, IS THE CABLE COATED?	IS CABLE ON ITS GUIDES THROUGHOUT CONVEYOR?
☐ YES ☐ NO	☐ YES ☐ NO
IS CABLE OPERATING SMOOTHLY?	IS CABLE CAUSING ANY WEAR ON CANS?
☐ YES ☐ NO	☐ YES ☐ NO
CONVEYOR SHUT-OFF SYSTEM TYPE?	IS CONVEYOR SHUT OFF SYSTEM WORKING PROPERLY?
☐ AUTOMATIC ☐ MANUAL	☐ YES ☐ NO

FIRM NAME	CF NO.	INSPECTION DATE(S)
DOES FIRM KEEP RECORD OF TIN STOCK USED FOR EACH LOT OF FINISHED CANS? ☐ YES ☐ NO	ARE CAN FLANGES *(both ends)* FREE FROM DEFECTS? ☐ YES ☐ NO	
DESCRIBE CONTAINER CLEANING METHOD		
PREPARATION OF PACKING MEDIUM		
GIVE FORMULA		
GIVE TIME/TEMPERATURES OF PREPARATION AND HOLDING		
IS EQUIPMENT ADEQUATELY CLEANED?		
ACIDIFICATION AND WATER ACTIVITY CONTROL		
FOR PARTIALLY ACIDIFIED *(above 4.6)* LACF PRODUCTS, HOW IS ACIDIFICATION PERFORMED AND CONTROLLED? *(See 113.81(e))*		
FOR WATER ACTIVITY CONTROLLED LACF PRODUCTS, HOW IS THE WATER ACTIVITY SPECIFIED IN THE SCHEDULED PROCESS ACHIEVED AND CONTROLLED? *(See 113.81(f))*		
FOR ACIDIFIED PRODUCTS, HOW IS ACIDIFICATION PERFORMED AND CONTROLLED? *(See 114.80(a)(1) through (a)(3))*		
FILLING		
GIVE METHOD(S) USED FOR EACH CONTAINER SIZE. *(See 113.81(c))*		
GIVE EQUIPMENT MODEL(S)/MANUFACTURER(S)		
IS EQUIPMENT ADEQUATELY CLEANED?		

FIRM NAME	CF NO.	INSPECTION DATE(S)

FILLING (cont'd)

ARE THERE ANY PROBLEMS WITH PRODUCT OVERLAYING EDGES OF CONTAINERS?

HOW IS HEADSPACING CONTROLLED?

IS THERE ANY POTENTIAL FOR DAMAGE TO CAN FLANGES DURING FILLING/HEADSPACING?

CONTROL OF CRITICAL FACTORS

(Per 113.40(a)(13), (b)(14), (c)(10), (d)(8), (e)(7), (f)(9), and (g)(4), critical factors specified in the scheduled processes for all retort types shall be measured and recorded at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process. Critical factors should be measured and recorded at intervals not to exceed 15 minutes. See 113.40(h), and (i) for regulations dealing with flame sterilizer systems and thermally processed foods in which critical factors such as water activity are used in conjunction with thermal processing.)

CRITICAL FACTORS *(As applicable)*	FREQUENCY OF CHECKS AND RECORDING
MAXIMUM DRAINED WEIGHT	
MAXIMUM FILL WEIGHT	
pH	
MINIMUM NET WEIGHT	
PERCENT SOLIDS	
MINIMUM HEADSPACE *(Agitating retorts)*	
PRODUCT CONSISTENCY *(Agitating retorts)*	
MINIMUM CLOSING MACHINE VACUUM *(for vacuum packed products)*	
FOR RETORTABLE POUCHES AND SEMI RIGID CONTAINERS:	
LIMITS OF VAPOR/AIR ENTRAPMENT	
RACKING CONFIGURATION: ORIENTATION OF CONTAINER	
CONTAINER THICKNESS RESTRICTION	
CONTAINER SEPARATION	
FLOW PASSAGE	
HEATING MEDIUM *(e.g., water, steam air, etc.)*	
CIRCULATION OF HEATING MEDIUM	
OTHER *(As specified in scheduled process)*	

FIRM NAME	CF NO.	INSPECTION DATE(S)

CLOSING

GIVE EQUIPMENT MODEL/MANUFACTURER/NUMBER OF SEAMER HEADS

DESCRIBE EQUIPMENT SANITATION AND MAINTENANCE

WHEN WERE THE CHUCK, ROLLERS, LIFTERS, BEARINGS, ETC. LAST REPLACED ACCORDING TO THE CLOSING MACHINE PREVENTIVE MAINTENANCE AND PARTS RECORDS?	ESTIMATED NUMBER OF CANS SEAMED SINCE LAST MAJOR OVERHAUL OF SEAMER

IF APPLICABLE, DESCRIBE "CLINCHING" OPERATION *(i.e., partial seaming operation sometimes performed prior to usual double seaming operation).*

WHAT IS THE METHOD OF HEADSPACE EXHAUST? *(See 113.81(d).*

IS THERE ANY POTENTIAL FOR CONTAINER DAMAGE *(especially seams)* DURING CLOSING OR DISCHARGE FROM CLOSING MACHINE?

HOW LONG MAY UNPROCESSED CONTAINERS BE HELD IN EVENT OF BREAKDOWN?

WHAT IS DISPOSITION IF TIME LIMITS ARE EXCEEDED?

DO CRATES. TRAYS. GONDOLAS, ETC. FOR HOLDING CONTAINERS FOR PROCESSING IN STEAM IN STILL REPORTS MEET THE REQUIREMENTS AND RECOMMENDATIONS OF 113.40(a)(9)?

HOW ARE CANS STACKED FOR PROCESSING? *(See 113.40(a)(9).)*

☐ HORIZONTAL ☐ VERTICAL ☐ RANDOM

IF PRODUCT IS STRATIFIED IN CONTAINERS *(e.g., whole leaf spinach, asparagus spears)* ARE THE CONTAINERS STACKED SO THE PLANE OF STRATIFICATION WILL BE VERTICAL DURING PROCESSING?

☐ YES ☐ NO, IF NO, HOW ARE CONTAINERS STACKED? _____

IS THERE ANY POTENTIAL FOR CONTAINER DAMAGE DUE TO OVERFILLING OF RETORT CRATES AND/OR STACKING OF OVERFILLED CRATES?

CONTAINER CLOSURE CHECKS

(Per 113.60, visual and teardown double seam exams shall be performed at intervals of sufficient frequency to ensure proper closure and maintenance of seam integrity. Visual exams of double seams should be performed at intervals not to exceed 30 minutes; teardown exams should not exceed 4 hours. For acidified foods, see 114.80(a)(4)).

FOR CANS. HOW OFTEN ARE VISUAL AND TEARDOWN SEAM EXAMINATIONS *(including factory ends, if applicable)* PERFORMED AND RECORDED?

VISUALLY EXAMINE AT LEAST ONE CAN FROM EACH SEAMER HEAD FOR CAN SEAM DEFECTS SUCH AS CUTOVERS, DEAD HEADS, FALSE SEAMS, ETC. SEE ILLUSTRATIONS IN IOM EXHIBIT 530G. REPORT RESULTS:

FIRM NAME	CF NO.	INSPECTION DATE(S)

CONTAINER CLOSURE CHECKS (cont'd)

FOR JARS, WHAT IS THE METHOD AND FREQUENCY OF CLOSURE INTEGRITY MEASUREMENTS AND FREQUENCY OF RECORDING?

DESCRIBE THE FIRM'S COLD WATER VACUUM RECORDS FOR JARS UTILIZING VACUUM CLOSURES: *(See 113.60(a)(2))*

FOR POUCHES OR SEMIRIGID CONTAINERS, WHAT IS THE METHOD AND FREQUENCY OF SEAL INTEGRITY MEASUREMENTS AND FREQUENCY OF RECORDING?

VISUALLY EXAMINE A REPRESENTATIVE NUMBER OF POUCHES OR SEMIRIGID CONTAINERS WITH HEAT SEALS FOR DEFECTS SUCH AS FOLDS, SEVERE WRINKLES, BLISTERS, AND TRAPPED PRODUCT IN SEALS. ALSO CHECK POUCHES FOR SEVERE DEFORMATION, GROSS OVERFILL, DELAMINATION AND LEAKS. REPORT RESULTS:

DO WRITTEN RECORDS OF LACF CONTAINER CLOSURE EXAMINATIONS *(see 113.60(a)(1) and 113.100(c))* INCLUDE THE FOLLOWING ITEMS *(Check blocks for included items.)*

☐ PRODUCT CODE ☐ DATE ☐ TIME OF EXAMINATION ☐ SEAM MEASUREMENTS PERFORMED

☐ CORRECTIVE ACTIONS TAKEN ☐ SIGNATURE OR INITIALS OF CLOSURE INSPECTOR AND REVIEWER

NOTE: Different measurements are required depending on the measurement system used. Check the blocks to indicate which measurements are recorded for the appropriate system.

MICROMETER

IS THIS METHOD USED? FOR EACH ITEM, 3 MEASUREMENTS, 120 DEGREES APART, EXCLUDING SIDE SEAM
☐ YES ☐ NO IF NO, DESCRIBE METHOD USED BELOW.

REQUIRED MEASUREMENTS

☐ COVER HOOK ☐ BODY HOOK ☐ WIDTH *(Length, Height)* ☐ TIGHTNESS *(Wrinkle)* ☐ THICKNESS

OPTIONAL MEASUREMENTS

☐ OVERLAP *(By calculation)* ☐ COUNTERSINK

SEAM SCOPE OR PROJECTOR

IS THIS METHOD USED? FOR EACH ITEM, 2 MEASUREMENTS AT DIFFERENT LOCATIONS, EXCLUDING SIDE SEAM
☐ YES ☐ NO IF NO, DESCRIBE METHOD USED BELOW

REQUIRED MEASUREMENTS

☐ BODY HOOK ☐ OVERLAP ☐ TIGHTNESS *(Wrinkle)* ☐ THICKNESS *(by micrometer)*

OPTIONAL MEASUREMENTS

☐ WIDTH *(Length, Height)* ☐ COVER HOOK ☐ COUNTERSINK

CODES

EXPLAIN THE CODE SYSTEM

DOES THE CODE IDENTIFY THE FOLLOWING *(See 113.60(c) and 114.80(b)) (Check the blocks for those items identified by the code.)*

☐ PRODUCT ☐ YEAR ☐ DAY ☐ PACKING PERIOD ☐ ESTABLISHMENT WHERE PACKED

THERMAL PROCESSING ROOM OPERATIONS

ARE OPERATING PROCESSES AND VENTING PROCEDURES POSTED OR READILY AVAILABLE AS REQUIRED BY 113.87(a)?
☐ YES ☐ NO IF NO, WHERE ARE THEY KEPT?

FIRM NAME	CF NO.	INSPECTION DATE(S)

THERMAL PROCESSING ROOM OPERATIONS

DOES THE POSTED PROCESS AGREE WITH THE FILED PROCESS OR WITH AN OPERATIONAL PROCESS GREATER THAN THE FILED PROCESS?
☐ YES ☐ NO IF NO, EXPLAIN DIFFERENCES

IS RETORT TRAFFIC SUFFICIENTLY CONTROLLED TO PREVENT MIX-UPS? *(See 113.87(b))*
☐ YES ☐ NO IF NO, EXPLAIN TRAFFIC FLOW

LIST BRAND(S) OF HEAT SENSITIVE INDICATORS USED AND HOW ATTACHED. *(See 113.87(b))*

ARE VISUAL CHECKS OF HEAT SENSITIVE INDICATORS MADE AFTER RETORTING?	ARE THE RESULTS OF CHECKS RECORDED? *(See 113.87(b))*
☐ YES ☐ NO	☐ YES ☐ NO

REPORT EXACT PROCEDURE FIRM USES TO DETERMINE INITIAL TEMPERATURE. *(See 113.87(c))*

FOR OPERATIONS USING WATER IN THE RETORT, WHAT PROVISIONS ARE MADE TO PREVENT WATER FROM LOWERING I.T.?

WHAT TIMING DEVICE(S) ARE USED TO TIME THE PROCESS AND WHEN WERE THEY LAST CHECKED FOR ACCURACY? *(See 113.87(d))*

DO CLOCK TIMES ON RECORDING THERMOMETER CHARTS CORRESPOND REASONABLY WITH TIMES ON WRITTEN PROCESSING RECORDS? *(See 113.87(e))* ☐ YES NO
IF NO, EXPLAIN

REPORT PRESSURE AND ADEQUACY OF STEAM SOURCE. *(See 113.87(f))*

LIST THE NUMBER, SIZE AND TYPE OF ALL THERMAL PROCESSING SYSTEMS IN THE PLANT HERE. USE COPIES OF FORM FDA 3146a, *(For processing in steam in still retorts)* OR BLANK SHEETS COVERING 21 CFR 113.40 REQUIREMENTS IN DETAIL *(for other retorts or processing systems)* TO REPORT THERMAL PROCESSING EQUIPMENT DATA.

FIRM NAME	CF NO.	INSPECTION DATE(S)

LIST YOUR ACTUAL THERMAL PROCESSING OPERATION OBSERVATIONS USING THESE OR OTHER APPROPRIATE HEADINGS

RETORT NO.	PRODUCT CODE	TIME STEAM ON	TIME/TEMP. VENT CLOSED	I.T.	TIME/TEMP. PROCESS START	RECORDER TEMP.	TIME PROCESS STOP	TIME/TEMP. SCHEDULED PROCESS

DESCRIBE ANY QUESTIONABLE PRACTICES OR DISAGREEMENT BETWEEN YOUR OBSERVATIONS AND FIRM'S RECORDS.

POST PROCESS HANDLING

IF CONTAINERS ARE WATER COOLED, WHAT IS THE SOURCE OF THE COOLING WATER?	WHAT IS THE CONCENTRATION OF CHLORINE OR OTHER CHEMICALS USED?
DESCRIBE ANY OTHER WATER TREATMENT USED *(See 113.60(b))*	HOW OFTEN IS CHLORINE *(or other chemicals used)* LEVEL CHECKED PER FIRM'S TESTING RECORDS AND YOUR OBSERVATIONS?
IF CONTAINERS ARE AIR COOLED, WHERE?	WHERE IS THE WATER SAMPLE COLLECTED?

ARE AIR COOLING CONTAINERS PROTECTED FROM CONTAMINATION FROM EMPLOYEE GARMENTS, RODENTS, BIRDS, WET POROUS SURFACES SUCH AS WOOD CRATES, ETC.? ☐ YES ☐ NO IF NO, EXPLAIN.

IF CONTAINERS ARE COOLED UNDER PRESSURE, DESCRIBE AIR SUPPLY AND CONTROLS.

FIRM NAME	CF NO.	INSPECTION DATE(S)

POST PROCESS HANDLING (cont'd)

DESCRIBE METHOD AND TYPE OF EQUIPMENT USED FOR CRATE UNLOADING, CAN UNSCRAMBLING, LABELING, AUTOMATIC CASE-UP, ETC.

IS THERE ANY POTENTIAL FOR CONTAINER DAMAGE FROM ROUGH HANDLING OR CONTAMINATION FROM STANDING WATER, ROUGH SPOTS, BARBS, ETC. ON CONTAINER HANDLING SURFACES? *(Set 113.60(d))* ☐ YES ☐ NO IF YES, REPORT THE TYPE, DEGREE AND FREQUENCY OF CONTAINER DEFECTS OR DAMAGE NOTED. DOCUMENT GROSS DEFECTS OR DAMAGE WITH PHOTOGRAPHS AND/OR SAMPLES. IF SAMPLES ARE COLLECTED, REPORT SAMPLE NUMBERS AND THE NUMBER OF CONTAINERS COLLECTED OUT OF THE TOTAL EXAMINED.

WHAT IS FIRM'S PROCEDURE IF SEAM OR SEAL PROBLEMS ARE FOUND AFTER THERMAL PROCESSING?

WHAT FACILITIES/PROCEDURES ARE AVAILABLE FOR CLEANING AND SANITIZING ALL POST PROCESSING CONTAINER HANDLING EQUIPMENT?

ARE THERE WRITTEN CLEANING AND SANITIZING PROCEDURES AND ACCOMPLISHMENT RECORDS?

☐ YES ☐ NO

RECORD DATA ENTRIES

ARE ALL RECORD DATA ENTRIES MADE AT THE TIME THE ACTUAL OPERATION OCCURS? *(See 113.100(a)).*
☐ YES ☐ NO IF NO, DESCRIBE YOUR OBSERVATIONS.

RECORDS FOR LACF PRODUCTS

DO THERMAL PROCESSING RECORDS INCLUDE THE FOLLOWING ITEMS, AS REQUIRED BY 113.100? CHECK EACH ITEM WHICH IS INCLUDED ON THE RECORDS.

☐ PRODUCT ☐ CODE ☐ DATE ☐ RETORT NO. ☐ CONTAINER SIZE ☐ APPROXIMATE NO. OF CONTAINERS PER CODING INTERVAL
☐ INITIAL TEMPERATURE ☐ ACTUAL PROCESSING TIME ☐ MERCURY THERMOMETER READINGS
☐ RECORDING THERMOMETER READINGS ☐ APPROPRIATE SIGNATURE OR INITIALS

LIST OTHER APPROPRIATE PROCESSING DATA INCLUDED

FIRM NAME	CF NO.	INSPECTION DATE(S)

RECORDS FOR LACF PRODUCTS (cont'd)

DO RECORDS ALSO INCLUDE THE FOLLOWING ADDITIONAL ITEMS ALSO REQUIRED FOR SPECIFIC PROCESSING SYSTEMS? CHECK EACH ITEM WHICH IS INCLUDED IN THE RECORDS.

STILL RETORTS ☐ TIME STEAM ON ☐ TIME TEMPERATURE IS UP TO PROCESSING TEMPERATURE

☐ TIME STEAM OFF ☐ VENTING TIME AND TEMPERATURE TO WHICH VENTED

AGITATING RETORTS

☐ FUNCTIONING OF CONDENSATE BLEEDER ☐ RETORT SPEED

HYDROSTATIC RETORTS

☐ TEMPERATURE IN STEAM CHAMBER BETWEEN STEAM/WATER INTERFACE AND LOWEST CONTAINER POSITION

☐ SPEED OF CONTAINER CONVEYOR CHAIN

☐ TEMPERATURE NEAR TOP AND BOTTOM OF EACH HYDROSTATIC WATER LEG *(when the scheduled process specifies maintenance of a particular temperature in hydrostatic water legs)*

ASEPTIC SYSTEMS

☐ PRODUCT TEMPERATURE IN HOLDING TUBE OUTLET, AS INDICATED BY TEMPERATURE INDICATING DEVICE AND TEMPERATURE RECORDER

☐ PRODUCT TEMPERATURE IN FINAL HEATER OUTLET, AS INDICATED BY TEMPERATURE RECORDER - CONTROLLER

☐ DIFFERENTIAL PRESSURE AS INDICATED BY DIFFERENTIAL PRESSURE RECORDER - CONTROLLER *(If product-to-product regeneration is used)*

☐ PRODUCT FLOW RATE, AS DETERMINED BY METERING PUMP OR FILLING AND CLOSING RATE

☐ STERILIZATION MEDIA FLOW RATE AND/OR TEMPERATURE

☐ RETENTION TIME OF CONTAINERS, AND CLOSURES WHERE APPLICABLE, IN THE STERILIZING EQUIPMENT

☐ STERILIZATION CYCLE TIMES AND TEMPERATURES *(where batch system is used for container and/or closure sterilization)*

FLAME STERILIZERS

☐ CONTAINER CONVEYOR SPEED ☐ SURFACE TEMPERATURE AT THE BEGINNING AND THE END OF THE HOLDING PERIOD ☐ NATURE OF CONTAINER

SYSTEMS RELYING ON CRITICAL FACTORS, SUCH AS WATER ACTIVITY, WITH THERMAL PROCESSING

☐ PRODUCT FORMULATION ☐ THERMAL PROCESS USED AND ASSOCIATED CRITICAL FACTORS ☐ OTHER CRITICAL FACTORS SCHEDULED PROCESS

☐ RESULTS OF a_w DETERMINATIONS

ARE RECORDING THERMOMETER CHARTS IDENTIFIED WITH THE FOLLOWING? CHECK INCLUDED ITEMS *(See 113.100(b))*

☐ DATE ☐ RETORT NUMBER ☐ APPROPRIATE SIGNATURE OR INITIALS

ARE ALL RECORDS REVIEWED WITHIN ONE WORKING DAY AFTER PROCESSING AND PRIOR TO RELEASE OF PRODUCT?

☐ YES ☐ NO IF NO, WHEN ARE THEY REVIEWED?_____

ARE THEY SIGNED OR INITIALED BY REVIEWER? ☐ YES ☐ NO

ARE ALL RECORDS RETAINED IN ACCORDANCE WITH 108.35(h) and 113.100(e)? ☐ YES ☐ NO IF NO, EXPLAIN

RECORDS FOR ACIDIFIED PRODUCTS

DO RECORDS INCLUDE THE FOLLOWING ITEMS REQUIRED BY 114.100? CHECK EACH ITEM WHICH IS INCLUDED IN THE RECORDS

☐ EXAMINATION OF RAW MATERIALS ☐ EXAMINATION OF PACKAGING MATERIALS

☐ EXAMINATIONS OF FINISHED PRODUCTS ☐ RECORDS OF SUPPLIERS GUARANTEES

☐ PRODUCT ☐ CONTAINER SIZE ☐ CODE ☐ DATE ☐ pH MEASUREMENTS ☐ OTHER CRITICAL FACTORS

ARE ALL APPROPRIATE RECORDS REVIEWED AND RETAINED FOR 3 YEARS AS REQUIRED BY 108.25(g) AND 114.100(e)?

☐ YES ☐ NO IF NO, EXPLAIN

SUMMARY OF RECORDS REVIEWED

LIST DATES OF RECORDS REVIEWED. *(See IOM Exhibit 645.2a)*

FIRM NAME	CF NO.	INSPECTION DATE(S)

PROCESSING DEVIATIONS

DOES THE FIRM MAINTAIN A SEPARATE FILE (OR LOG) OF PROCESSING DEVIATIONS, AS REQUIRED BY 113.89 AND 114.100(C)?

☐ YES ☐ NO

IF PROCESSING DEVIATIONS DID OCCUR WHAT ACTION DID THE FIRM TAKE IN EACH CASE? (SET ASIDE AND HOLD? REPROCESS? DESTROY? EVALUATE?) *(See 113.89 and 114.89)* REPORT FINDINGS BELOW

NOTE: PROCESSING DEVIATIONS INCLUDE FAILURE TO MAINTAIN CRITICAL FACTORS WITHIN ESTABLISHED LIMITS; e.g. MAXIMUM RATIO OF DRAINED WEIGHT TO NET WEIGHT FOR SPINACH, MAXIMUM FILL WEIGHT AND METHOD OF FILL FOR MUSHROOMS; ETC.

FIRM NAME	CF NO.	INSPECTION DATE(S)

WAREHOUSING

HOW ARE FINISHED CONTAINERS PROTECTED FROM CONTAMINATION FROM WATER, BIRDS, RODENTS, ETC.?

DOES THE FIRM INCUBATE LOTS OR PORTIONS OF LOTS PRIOR TO DISTRIBUTION? IF YES, EXPLAIN THE PRACTICE IN DETAIL

DETAIL ANY EVIDENCE OF SPOILAGE OR ABNORMAL CONTAINERS IN THE WAREHOUSE AREA BY CODE LOT NUMBER *(Examine any suspect codes identified through record review. If no lots are suspect randomly select several codes for warehouse examination.)* REVIEW RECORDS FOR ANY ABNORMAL CODES IDENTIFIED THROUGH WAREHOUSE INSPECTION.

FOR EXAMINED RETORTED POUCHES OR HEAT SEALED SEMIRIGID CONTAINERS, DETAIL ANY FINDINGS OF SEAL DEFECTS SUCH AS FOLDS, SEVERE WRINKLES, BLISTERS, AND TRAPPED PRODUCT. ALSO REPORT FINDINGS OF SEVERE DEFORMATION, GROSS OVERFILL, DELAMINATION, LEAKS, AND EXCESSIVE SEAL CREEP AND DISTORTION WHICH COULD INDICATE INADEQUATE CONTROL OF PRESSURE COOLING.

FIRM NAME	CF NO.	INSPECTION DATE(S)

COMPLAINT FILE REVIEW

REPORT DETAILS OF ANY SIGNIFICANT COMPLAINTS, ESPECIALLY ANY COMPLAINTS SUGGESTIVE OF UNDERPROCESSING, SUCH AS ILLNESS OR ABNORMAL CONTAINERS.

RECALL PROCEDURES

DOES THE FIRM HAVE A WRITTEN RECALL PROCEDURE WHICH COMPLIES WITH THE REQUIREMENTS OF 108.25(e) OR 108.35(f)?
☐ YES ☐ NO IF NO, EXPLAIN

DOES THE FIRM MAINTAIN INITIAL DISTRIBUTION RECORDS AS REQUIRED BY 113.1OO(d) AND 114.100(d)? ☐ YES ☐ NO
IF NO, EXPLAIN

PROMOTION AND DISTRIBUTION

SEE IOM 592.31(m) FOR REQUIRED INFORMATION

REFUSALS

GIVE DETAILS OF ALL REFUSALS

SAMPLES

LIST SAMPLE NUMBER(S) WITH PRODUCT(S) COLLECTED

FIRM NAME	CF NO.	INSPECTION DATE(S)

EXHIBITS

LIST EXHIBITS

DISCUSSION WITH MANAGEMENT

REPORT PERSONS (NAME AND TITLE) WITH WHOM FDA-483 AND OTHER FINDINGS WERE DISCUSSED. LIST ALL RECOMMENDATIONS, WARNINGS, OR SUGGESTIONS GIVEN OR MADE TO MANAGEMENT AND REPORT MANAGEMENT'S RESPONSE.

SIGNATURE OF INVESTIGATOR

SIGNATURE OF INVESTIGATOR